UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 09/206,249 | 12/07/1998 | MIRI SEIBERG | JBP438 | 5255 |

7590 10/23/2006

PHILIP S. JOHNSON, ESQ.
JOHNSON & JOHNSON
ONE JOHNSON & JOHNSON PLAZA
NEW BRUNSWICK, NJ 08933-7003

| EXAMINER | |
|---|---|
| MELLER, MICHAEL V | |
| **ART UNIT** | **PAPER NUMBER** |
| 1655 | |

DATE MAILED: 10/23/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 09/206,249 | SEIBERG ET AL. | |
| | Examiner | Art Unit | |
| | Michael V. Meller | 1655 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *23 August 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *75-85* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *75-85* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

## DETAILED ACTION

### *Claim Rejections - 35 USC § 112*

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 75-85 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Applicant's use of the term "soy product" or "soybean milk", "soybean derivative", "serine protease inhibitor", "soybean paste", etc. are vague and indefinite. It would be much clear if applicant simply used "soybean extract" of "an extract from soybean" to describe the extract since that is what it is. Applicant's in the last interview held which they note in their last response, they even noted that they called the extract 'soybean milk" because it looked like milk. This was noted as not the right term of art. Thus, applicant's are requested to change all terms to "soybean extract" or "an extract from soybean".

Applicant has changed "soy product" to "soy extract" and "soybean derivative" to "soybean extract" but applicant still has not properly claimed "serine protease inhibitor". Further, applicant is still claiming a "soybean milk". As was discussed in the interview, it

would be clearer for applicant to simply claim the extract as just that an extract. This is the art recognized term used in the plant extract art. Further, to refer to the soybean extract as milk is confusing since it is not milk it just appears as milk, thus a misleading and inaccurate term. It further is not clear how a soy extract can comprise a soybean extract or a serine protease inhibitor. It makes sense that a soy extract would contain a soybean extract but not that a serine protease inhibitor and a soybean extract are mutually exclusive. A soybean extract would have the serine protease inhibitor in it.

Thus, the claims remain as vague and indefinite.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 75-85 are rejected under 35 U.S.C. 102(a or b) as being anticipated by Collins (title, col. 2, lines 15-25), Motitschke et al. (col. 7, lines 5-50), JP 408143442 (abstract), CN 1081899 (abstract), JP 04283518 (abstract) or JP 410226642 (abstract).

The references each teach an extract of soybean used to topically treat psoriasis, periodontal disease and eczema. Applicant refers to this extract as soybean milk in their claims, but it is clear from applicant's own specification that the extract is an extract of soybean, not soybean milk. Applicant even admitted in the recent interview that they refer to in their current response that they refer to the soybean extract as soybean milk because it looks "milky". Thus, the soybean extract of the references and that claimed are one and the same.

Applicants argue that JP '442 will not contain the active STI proteins because applicant feels that the protein would not have diffused out of the soybean and into the aqueous medium. Applicant also argues that the temperatures of up to 100 $^0$ C would denature the protein. Upon close inspection of JP '442, it is clear that the exposure to the water can be only 5 minutes at 5$^0$ C which would not cause denaturing. Further, JP also teaches defatted soybeans which would be extracts, thus reading on the claims.

Next, applicant argues that CN relates to soybean oil which they argue would not contain proteins in it. While this is not agreed with, the claims claim soy extract having active trypsin activity which clearly the oil would. Simply because the applicant states that proteins may not be in the oil does not negate the fact that the oil has the claimed

activity. Collins is also argued in this fashion by applicant in terms of its disclosure of soybean oil.

Applicant argues that Motitschke teaches denaturing of the brewer's grains, but upon closer inspection of the reference it is clearer that actually the reference uses soybean oil which was not denatured. Thus, the above comments concerning oils apply.

Applicant argues that JP '518 does not contain STI proteins because applicant feels that at 50-60 $^{0}$ C the proteins are denatured. First of all, there is no evidence on the record that, that is so. Secondly, these temperatures are not that high to cause denaturation.

Applicant next argues that in JP '642 the genistein which they disclose must be denatured. There is no evidence of this in JP '642 and applicant has provided nothing on the record to prove such an allegation.

Thus, the references continue to meet the claimed invention.

This is a RCE of applicant's earlier Application No. 09/206,249. All claims are drawn to the same invention claimed in the earlier application and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the earlier application. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action in this case. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no, however, event will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael V. Meller whose telephone number is 571-272-0967. The examiner can normally be reached on Monday thru Thursday: 9:30am-6:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Michael V. Meller
Primary Examiner
Art Unit 1655

MVM